



6097 '98 SEP 11 P1:53

August 31, 1998

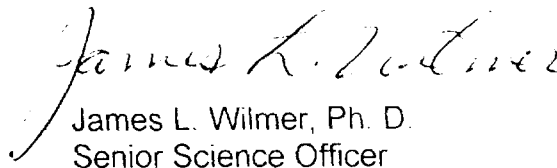
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204

Dear Sir/Madam:

I have enclosed notification forms which are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C. F. R. §101.93. Thirteen health and nutrition products are discussed and presented on separate forms. As such, I have listed the structure-function statements found on product labels and associated support literature, identified the dietary ingredient or supplement that is the subject of the statement, and identified the brand name of each supplement for which a statement is made.

Thank you.

Sincerely,


James L. Wilmer, Ph. D.
Senior Science Officer

Enclosures: 1 original and 2 copies

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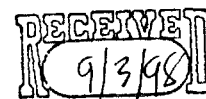


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NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93



This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Maintain One**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Benefits: Helps increase the production of glycogen for potential energy; helps reduce food intake; inhibits the production of fats and cholesterol from carbohydrates."—bottle label.

Statement 2: "Maintain One is a chewable natural food supplement that is used to improve the rate of effective weight loss and aid in long-term weight maintenance."—brochure.

Statement 3: "Studies show that HCA [(-) hydroxycitric acid] can help curb your appetite, reduce food intake, and inhibit the production of fat and cholesterol from carbohydrates."—brochure.

Statement 4: "*Gymnema sylvestre* makes sweet food taste less sweet, resulting in fewer sugar cravings."—brochure.

Statement 5: "In addition, *Rhizoma atractylodes* and *Fructus citrii aurantii* help your body digest your food better, making the nutrients in your food more effective and curbing your appetite."—brochure.

Statement 6: "Helps reduce elevated blood fat levels."—brochure.

Statement 7: "Helps convert excess glucose into glycogen."—brochure.

Statement 8: "Increases the storage of energy as glycogen in the liver and muscle."—brochure.

Statement 9: "Helps you have control over your appetite."—brochure.

Statement 10: "Helps increase thermogenesis, the burning of calories for heat."—brochure.

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Statement 11: "Reduces food intake."—brochure.

Statement 12: "Inhibits the production of fats and cholesterol."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>
2.	Maintain One is composed of <i>Garcinia cambogia</i> (a source of (-) hydroxycitric acid [CitriMax™]), <i>Rhizoma atractylodes</i> , <i>Fructus citrii aurantii</i> , Brewer's yeast
3.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>
4.	<i>Gymnema sylvestre</i>
5.	<i>Rhizoma atractylodes</i> and <i>Fructus citrii aurantii</i>
6.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>
7.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>
8.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>
9.	Maintain One composed of <i>Garcinia cambogia</i> (a source of (-) hydroxycitric acid [CitriMax™]), <i>Rhizoma atractylodes</i> , <i>Fructus citrii aurantii</i> , Brewer's yeast
10.	Maintain One composed of <i>Garcinia cambogia</i> (a source of (-) hydroxycitric acid [CitriMax™]), <i>Rhizoma atractylodes</i> , <i>Fructus citrii aurantii</i> , Brewer's yeast
11.	Maintain One composed of <i>Garcinia cambogia</i> (a source of (-) hydroxycitric acid [CitriMax™]), <i>Rhizoma atractylodes</i> , <i>Fructus citrii aurantii</i> , Brewer's yeast
12.	(-) hydroxycitric acid [CitriMax™] from <i>Garcinia cambogia</i>

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	Maintain One	bottle label
2.—12.	Maintain One	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998

By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **ThermoChrome Select**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "A weight-management and vitality supplement."—bottle label.

Statement 2: "Increases energy and contributes to your success on any safe weight-loss program."—trial pack label.

Statement 3: "Chromium picolinate and chromium proteinate increase the blood concentration of glucose tolerance factor and help to prevent sugar cravings and the loss of lean muscle mass while dieting."—trial pack label.

Statement 4: "L-Carnitine functions in the transport of fatty acids across the mitochondrial membranes and promotes energy production."—trial pack label.

Statement 5: "Ephedrine alkaloids increase the basal metabolic rate and, in combination with the herbal formula, promote thermogenesis."—trial pack label.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.—2.	ThermoChrome Select composed of the following ingredients: L-carnitine, boron proteinate, chromium proteinate, chromium picolinate, Ma Huang (<i>Ephedra sinensis</i>), white willow bark, Siberian ginseng (<i>Eleutherococcus senticosus</i>), <i>Ginkgo biloba</i> , ginger, gotu kola, beet powder, kelp, saw palmetto, hawthorn berry
3.	chromium picolinate and chromium proteinate
4.	L-carnitine
5.	ephedrine alkaloids in <i>Ephedra sinensis</i> in combination with the other ingredients in ThermoChrome Select

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The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	ThermoChrome Select	bottle label
2.—5.	ThermoChrome Select	trial pack label

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **ThermoChrome 5000**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Look and feel better with more energy."—bottle label.

Statement 2: "Activates thermogenesis."—brochure.

Statement 3: "Stimulates your body's basal metabolism."—brochure.

Statement 4: "Helps preserve lean body mass while dieting."—brochure.

Statement 5: "Helps control sugar and carbohydrate cravings."—brochure.

Statement 6: "Helps control your appetite."—brochure.

Statement 7: "Provides extra energy without caffeine."—brochure.

Statement 8: "L-Carnitine works synergistically with the chromium picolinate in ThermoChrome 5000 to induce thermogenesis, promote a better glucose tolerance level, control or eliminate sugar cravings, and preserve lean muscle mass while dieting."—brochure.

Statement 9: "Increases energy and contributes to your success on any safe weight-loss program."—trial pack label.

Statement 10: "Chromium picolinate and chromium proteinate help effect glucose tolerance level, sugar cravings, and help prevent loss of lean muscle mass while dieting."—trial pack label.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

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<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.—7.	ThermoChrome 5000 composed of the following ingredients: <i>Sida cordifolia</i> (a source of ephedrine alkaloids), L-carnitine, boron proteinate, chromium proteinate, chromium picolinate, white willow bark, Siberian ginseng (<i>Eleutherococcus senticosus</i>), <i>Ginkgo biloba</i> , ginger root, gotu kola, beet powder, kelp (a source of iodine), saw palmetto berry, hawthorn berry
8.	L-carnitine and chromium picolinate
9.	ThermoChrome 5000 is composed of the following ingredients: <i>Sida cordifolia</i> (a source of ephedrine alkaloids), L-carnitine, boron proteinate, chromium proteinate, chromium picolinate, white willow bark, Siberian ginseng (<i>Eleutherococcus senticosus</i>), <i>Ginkgo biloba</i> , ginger root, gotu kola, beet powder, kelp (a source of iodine), saw palmetto berry, hawthorn berry
10.	chromium picolinate and chromium proteinate

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	ThermoChrome 5000	bottle label
2.—8.	ThermoChrome 5000	brochure
9.—10.	ThermoChrome 5000	trial pack label

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **ThermoChrome Booster**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Look and feel better with more energy."—bottle label.

Statement 2: "ThermoChrome Booster can be used by itself, or it can be used to boost the ThermoChrome 5000 or 10000 formulation and give you that extra jolt of energy."—brochure.

Statement 3: "Look and feel better with more energy."—trial pack label

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.—3.	ThermoChrome Booster is composed of the following ingredients: <i>Sida cordifolia</i> (a source of ephedrine alkaloids), Yerba maté (a source of caffeine), parsley, <i>Cascara sagrada</i> bark, ginger root, <i>Capsicum</i> , L-carnitine, niacin, chromium picolinate

The following identifies the brand name of each supplement for which a statement is made:

Statement Number(s)	Brand Name	Label or Labeling
1.	ThermoChrome Booster	bottle label
2.	ThermoChrome Booster	brochure
3.	ThermoChrome Booster	trial pack label

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I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **ThermoChrome 10000**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Look and feel better with more energy."—bottle label.

Statement 2: "This powerful combination provides extra energy, enhanced stamina, and suppression of appetite and sugar cravings."—brochure.

Statement 3: "ThermoChrome 10000 utilizes alternative herbal ingredients that achieve energy and weight management by helping to improve the body's overall metabolic functions of digestion, elimination, assimilation, cleansing, and thermogenesis."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.—3.	ThermoChrome 10000 is composed of the following ingredients: <i>Sida cordifolia</i> (a source of ephedrine alkaloids), Yerba maté (a source of caffeine), pearl powder, hawthorn berry, <i>Cinnamon ramulas</i> , <i>Angelica dahurica</i> , peppermint, lemon verbena, <i>Panax ginseng</i> , <i>Astragalus</i> , <i>Angelica sinensis</i> , ginger root, chamomile, <i>Bupleurum</i> , herba sargassi (seaweed), pericarpium citri, licorice root, chicory, L-carnitine, chromium picolinate, potassium phosphate

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The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	ThermoChrome 10000	bottle label
2.—3.	ThermoChrome 10000	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998

By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Oxygen Plus**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "When used in accordance with the directions, Oxygen Plus anti-oxidants help to protect from the effects of free radical damage caused by exposure to sunlight, X-rays, ozone, tobacco smoke, car exhaust and other environmental pollutants."—bottle label.

Statement 2: "The natural antioxidant, anti-aging breakthrough."—brochure.

Statement 3: "Bolsters the body's own defenses against diseases associated with free radical damage from environmental pollutants, stress and the sun's ultraviolet rays."—brochure.

Statement 4. "Oxygen PlusTM is serious nutrition with a solid scientific foundation that bolsters the body's defenses against the ravages of time.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.—4.	Oxygen Plus TM is composed of the following ingredients: vitamin C (ascorbate), vitamin A (<i>beta</i> -carotene precursor), vitamin E (d- <i>alpha</i> -tocopherol succinate), green tea extract, <i>Ginkgo biloba</i> extract, milk thistle (<i>Maria</i>), glutathione, selenium, bilberry

Also see docket 97S-0163

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The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	Oxygen Plus	bottle label
2.—4.	Oxygen Plus	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/88

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix Antioxidant Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Take this in addition to your MultiTech Formula and B12 Special Formula for protection against harmful free radicals."—brochure.

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.	Isotonix Antioxidant Formula is composed of the following ingredients: vitamin A (<i>beta</i> -carotene precursor), vitamin C (ascorbic acid), vitamin E (acetate), potassium bicarbonate, selenium (amino acid chelate); base ingredients include fructose, dextrose, citric acid, maltodextrin, silica, calcium sulfate, fruit pectin, and natural lemon-lime flavor

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	Isotonix Antioxidant Formula	brochure

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I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

RECEIVED
9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix B-12 Special Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "B12 helps reduce the effects of stress and depression, helps prevent 'tired blood' (anemia), and provides extra energy."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.	Isotonix B12 Special Formula is composed of the following ingredients: vitamin B-12 (cobalamin), folic acid, magnesium carbonate, potassium bicarbonate; base ingredients include fructose, dextrose, citric acid, maltodextrin, silica, calcium sulfate, fruit pectin, and natural lemon-lime flavor

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	Isotonix B12 Special Formula	brochure

Also see docket 975-0163

61007

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix Vitamin C Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Vitamin C protects against infectious disease, including the common cold and influenza, by strengthening the immune system."—brochure.

Statement 2: "It [vitamin C] also is a helper in the synthesis of collagen, which strengthens the cardiovascular system."—brochure.

Statement 3: "Vitamin C protects against hypersensitivity (exaggerated responses to allergenic substances) and periodontal disease."—brochure.

Statement 4. "Through its powerful antioxidant property, vitamin C promotes a vitamin-sparing effect, particularly with vitamin E and folic acid."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.—4.	vitamin C (ascorbic acid)

The following identifies the brand name of each supplement for which a statement is made:

Statement Number(s)	Brand Name	Label or Labeling
1.—4.	Isotonix Vitamin C Formula	brochure

Also see docket 975-0163

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I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
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RECEIVED
9/3/98

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix Isochrome Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Isochrome is a unique combination of vitally important compounds that provides 200 mcg of chromium supplementation, promoting efficient insulin activity and resulting in hunger control, metabolic enhancement, and maintenance of lean muscle mass."—brochure.

Statement 2: "Isochrome has L-carnitine to enhance fat metabolism and promote energy and stamina, and 60 mg of co-enzyme Q₁₀, essential for virtually all energy production because it facilitates transference of electrons in the energy cycle in the mitochondria."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.	Isotonix Isochrome Formula is composed of the following ingredients: chromium picolinate, chromium arginate, L-carnitine, boron amino acid chelate, potassium bicarbonate, vitamin B ₂ (riboflavin), vitamin B ₆ (pyridoxine HCl), coenzyme Q ₁₀ , lipase; the base ingredients include: fructose, glucose, vitamin A (as <i>beta</i> -carotene precursor), maltodextrin, malic acid, citric acid, calcium sulfate, fruit pectin, silica, and natural lemon-lime flavor.
2.	L-carnitine, co-enzyme Q ₁₀

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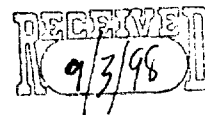
The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.—2.	Isotonix Isochrome Formula	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93



This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Isotonix OPC-3 (Oligomeric Proanthocyanidins)**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "These bioflavonoids have numerous functions in the body that include, but are not limited to, being powerful antioxidants crucial in supporting the circulatory system."—brochure.

Statement 2: "They strengthen the capillaries and enhance vitamin C and vitamin E functions."—brochure.

Statement 3: "Most importantly, OPC-3 is a super-effective free radical neutralizer."—brochure.

Statement 4: "In addition, red wine extract contains high levels of other polyphenols that are beneficial in counteracting free radical damage."—information handout glossy.

Statement 5: "As a homeopathic substance, OPC-3 is anti-inflammatory and anti-histaminic as an H3 enzyme blocker."—information handout glossy.

Statement 6: "It [OPC-3] acts against gum bleeding (loose teeth), protects the liver from lipid oxidation during excessive alcohol intake, protects against ionizing radiation (including x-rays and U. V. B.), and protects other essential biological functions."—information handout glossy.

Statement 7: "As a food supplement, OPC-3 protects unsaturated fats (the lipid constituents of cell membranes), particularly the lipids found in the retina of the eye and brain cells."—information handout glossy.

Statement 8: "It [OPC-3] is recommended in hypocaloric diets in which the few remaining unsaturated fats come under heavy attack from free radicals."—information handout glossy.

Also see docket 975-0163

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Statement 9: "As a cosmetic, OPC-3 protects the skin against early aging and free oxygen radicals produced by U. V. radiation."—information handout glossy.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
1.—9.	Isotonix OPC-3 is composed of the following ingredients: grape seed extract, red wine extract, pine bark extract, bilberry extract, citrus extracts; the base ingredients include: fructose, glucose, maltodextrin, citric acid, calcium sulfate, apple pectin, silica, potassium bicarbonate.

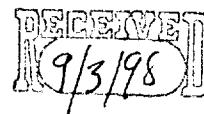
The following identifies the brand name of each supplement for which a statement is made:

Statement Number(s)	Brand Name	Label or Labeling
1.—3.	Isotonix OPC-3	brochure
4.—9.	Isotonix OPC-3	information handout glossy

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
Senior Science Officer

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**



This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **7605 Business Park Drive, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Ultimate Aloe Drink**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Helps strengthen the immune system."—brochure.

Statement 2: "Provides extra energy."—brochure.

Statement 3: "Through a process of endocytosis, these long-chained carbohydrates can enter cells and contribute to many body functions such as our immune system, energy production, and getting oxygen into our cells and waste products out."—brochure.

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.	polysaccharides (e.g., acemannan) in Ultimate Aloe Drink (concentrate from <i>Aloe vera</i> , citric acid, ascorbic acid, potassium sorbate, sodium benzoate)
2.	monosaccharides and disaccharides in Ultimate Aloe Drink
3.	polysaccharides in Ultimate Aloe Drink

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The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.—3.	Ultimate Aloe Drink	brochure

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 31, 1998 By: James L. Wilmer
James L. Wilmer, Ph. D.
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